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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Reinhard Doenges

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RICHARD S. ROBERTS  
ROBERTS & ROBERTS  
P.O. BOX 484  
PRINCETON, NJ 08542

EXAMINER

WHITE, EVERETT NMN

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/955,864	<b>Applicant(s)</b> DOENGES ET AL.	
	<b>Examiner</b> EVERETT WHITE	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☒ Certified copies of the priority documents have been received in Application No. 09/427,351.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 1, 2004 has been entered.
2. The response filed June 1, 2004 has been received, entered and carefully considered. The response affects the instant application accordingly:
  - (A) Claims 3 and 4 have been amended;
  - (B) Comments regarding Office Action have been provided drawn to:
    - (i) 112, 2<sup>nd</sup> paragraph rejection, which has been withdrawn;
    - (ii) 102(b) rejections, which are maintained for the reasons of record.
3. Claims 1-8 are pending in the case.
4. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

#### ***Claim Objections***

5. Claim 8 is objected to because of the following informalities: In Claim 8, line 2, the term "Cl<sub>2</sub>" should be changed to -- C<sub>12</sub> --. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112, 1<sup>st</sup> Paragraph***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants set forth claim language which includes a water-soluble ionic cellulose ether having a degree of hydroxyalkylation greater than 2.3. However, teachings in the instant specification reciting a degree of hydroxyalkylation greater than 2.3 has not been seen in the instant specification. Hence, the insertion of this language in the instant claims appears to set forth new matter which is improper under 35 U.S.C. 112, 1<sup>st</sup> paragraph.

8. Applicant's arguments with respect to Claims 1-8 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> Paragraph***

9. Claims 1 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 7 set forth a degree of hydroxyalkylation for the cellulose ether thereof as being greater than 2.3 and further sets forth having 1.0 alkyl group per anhydroglucose unit substitution. Since cellulose is the starting material used in the process of Claim 7 (which produces the product of Claim 1), the maximum degree of substitution for cellulose is 3 since cellulose only sets forth 3 hydroxy groups available for substitution. However, the substituted groups per anhydroglucose unit set forth in Claims 1 and 7 adds up to be more than 3, which renders said claims indefinite. The maximum amount of alkyl substitution per anhydroglucose unit can only be 0.69 or the degree of hydroxyalkylation for the cellulose ether can only be 1.99 (assuming that the 0.01 sulfoalkyl group per anhydroglucose unit set forth in the instant claims is correct).

10. Applicant's arguments with respect to Claims 1 and 7 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 102***

11. Claims 2-8 stand rejected under 35 U.S.C. 102(b) as being anticipated by Miyajima et al (EP 781,780) for the reasons set forth on pages 3-5 in the Office Action mailed October 27, 2003.

Applicant's arguments filed June 1, 2004 have been fully considered but they are not persuasive. Applicants argue against the rejection on the ground that the Miyajima et al patent discloses the degree of sulfoalkyl substitution to be in the range of 0.01 to 2.0 wherein the present invention requires a much narrower 0.01 to 0.1 sulfoalkyl group per anhydroglucose unit. A similar argument is presented for the degree of hydroxyalkylation wherein the Miyajima et al patent discloses a degree of hydroxyalkylation in the range from 0.1 to 10, wherein the present invention requires a degree of hydroxyalkylation which is greater than 2.3. This argument is not persuasive since the degrees of substitution for the sulfoalkyl group and the hydroxyalkyl group disclosed in the instant claims are covered in the Miyajima et al patent, which is seen to anticipate the instantly claimed compounds and process of preparation. Furthermore, arguments with regard to the claimed cellulose ether having unexpected advantageous drip property when set forth in a pain formulation is not persuasive since one of ordinary skill in this art would expect analogous compounds to have analogous properties.

Applicants further argue that the degree of hydroxyalkylation and degree of substitution of sulfoalkylation disclosed in the Miyajima et al patent set forth broad ranges that are theoretical and has not been supported by experimental results in the Miyajima et al patent. This argument is not persuasive because the claimed ranges for the substituted groups in the cellulose ether overlaps those of the prior art and no unexpected properties are shown or a teaching away from the claimed range. *In re Malagari* (CCPA 1974) 499 F2d 1297, 182 USPQ 549.

Accordingly, the rejection of Claims 2-8 under 35 U.S.C. 102(b) as being anticipated by the Miyajima et al patent is maintained for the reasons of record.

12. Claim 1 stands rejected under 35 U.S.C. 102(b) as being anticipated by Miyajima et al (EP 781,780) for the reasons set forth on pages 5 and 6 of the Office Action mailed October 27, 2003.

13. Applicant's arguments filed June 1, 2004 have been fully considered but they are not persuasive. Applicants argue against the rejection for the reasons presented in the above rejection, but are not persuasive for the same reasons recited above.

Applicants additionally argue that the starting material in the present invention differs from the starting material of the Miyajima et al patent. Applicants argue that Miyajima et al starts with hydroxyethylcellulose wherein the present invention starts with a cellulose material. This argument is not persuasive. See page 5, lines 11 and 12 of the Miyajima et al patent wherein cellulose may be used as the starting material to prepare the cellulose ethers thereof.

Accordingly, the rejection of Claim 1 under 35 U.S.C. 102(b) as being anticipated by the Miyajima et al patent is maintained for the reasons of record.

### ***Summary***

14. All the claims are rejected.

### ***Examiner's Telephone Number, Fax Number, and Other Information***

15. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at [www.uspto.gov](http://www.uspto.gov) and click on the button "Patent Electronic Business Center" for more information.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for this Group is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

  
E.White

  
James O. Wilson  
Supervisory Primary Examiner  
**Technology Center 1600**